Press Release

New Sarclisa subcutaneous formulation met co-primary endpoints in the IRAKLIA phase 3 study in multiple myeloma

- Sarclisa SC formulation added to Pd for the treatment of R/R MM met the co-primary endpoints in the IRAKLIA phase 3 study, demonstrating non-inferiority compared to Sarclisa IV
- IRAKLIA is the first global phase 3 study to evaluate the SC administration of a cancer treatment via an OBDS
- OBDS is an alternative delivery method designed to improve the patient experience and currently available SC administration

Paris, January 9, 2025. Results from the investigational, randomized, open-label IRAKLIA phase 3 study demonstrated that Sarclisa administered at a fixed dose subcutaneously (SC) via an on-body delivery system (OBDS) in combination with pomalidomide and dexamethasone (Pd) met its co-primary endpoints of non-inferior objective response rate (ORR) and observed concentration before dosing (C trough) at steady state compared to intravenous (IV) Sarclisa administered at a weight-based dose in combination with Pd in patients with relapsed or refractory multiple myeloma (R/R MM). Key secondary endpoints, including very good partial response (VGPR), incidence rate of infusion reactions and C trough at cycle 2 were also achieved. The study is ongoing, and the full results will be presented at a forthcoming medical meeting.

> ***Sikander Ailawadhi, MD***
> Professor of Medicine, Division of Hematology/Oncology at Mayo Clinic Florida and principal investigator of the study
> *"The consistent overall response rate and comparable efficacy and safety profile observed in the IRAKLIA study for subcutaneous Sarclisa represent an exciting advancement, offering insight into a potential new administration option for patients. The results from IRAKLIA, in patients with relapsed or refractory multiple myeloma, support the potential of an on-body delivery system to help ease the delivery of a new formulation without impacting patient outcomes."*

The IRAKLIA study was conducted using Enable Injections' enFuse® hands-free OBDS, which was designed to administer high-volume medicines subcutaneously through an automated drug delivery technology. The enFuse device leverages a hidden and retractable needle that is thinner compared to commonly used SC injection needles.

> ***Houman Ashrafian, MD, PhD***
> Executive Vice President, Head of Research and Development at Sanofi
> *"We are fueled by our focus on innovation and finding best-in-class solutions to help ease the burden of disease for patients. The IRAKLIA study results are a prime example of what's driving our scientific engine. Being able to possibly bring a novel option that helps reduce time in a healthcare facility is driven by our patient and provider-centric mindset. We look forward to sharing full results and working to bring this new advancement to the multiple myeloma community."*

Additional studies evaluating Sarclisa SC formulations across different combinations and lines of therapy are ongoing. The safety and efficacy of Sarclisa SC and the enFuse device have not been evaluated by any regulatory authority outside of their approved indications. Regulatory submissions in the US and in the EU are planned during the first half of 2025.

About the IRAKLIA study

IRAKLIA is a randomized, open-label, pivotal phase 3 study evaluating the non-inferiority of Sarclisa SC formulation administered at a fixed dose subcutaneously via an OBDS versus weight-

based dosed Sarclisa IV in combination with Pd in adult patients with R/R MM. The study enrolled 531 patients across 252 global sites, who were equally randomized to receive Sarclisa SC or IV in combination with Pd for 28-day cycles until disease progression, unacceptable adverse events (AEs), participant request to discontinue therapy or any other reason, whichever came first. In the SC arm, Sarclisa was administered at a fixed dose SC weekly for four weeks during the first cycle and every two weeks for subsequent cycles. In the IV arm, Sarclisa was administered at a weight-based dose via IV infusion weekly for four weeks during the first cycle and every two weeks for subsequent cycles. The study enrolled adult patients with MM who have received at least one prior line of therapy, including lenalidomide and a proteasome inhibitor.

The co-primary outcomes being assessed are ORR, defined as the proportion of patients with stringent complete response, complete response, VGPR, and partial response (PR) according to the 2016 IMWG criteria assessed by Independent Review Committee (IRC), and observed C trough at steady state, defined as observed Sarclisa plasma concentrations.

About Enable Injections

Based in the US (Cincinnati, Ohio), Enable Injections is a global healthcare innovation company committed to improving the patient treatment experience through the development and manufacturing of enFuse. enFuse is an innovative wearable drug delivery platform that is designed to deliver large volumes of pharmaceutical and biologic therapeutics via subcutaneous administration, with the aim of improving convenience, supporting superior outcomes, and advancing healthcare system economics. For more information, visit https://enableinjections.com.

About Sarclisa

Sarclisa (isatuximab) is a CD38 monoclonal antibody that binds to a specific epitope on the CD38 receptor on MM cells, inducing distinct antitumor activity. It is designed to work through multiple mechanisms of action including programmed tumor cell death (apoptosis) and immunomodulatory activity. CD38 is highly and uniformly expressed on the surface of MM cells, making it a target for antibody-based therapeutics such as Sarclisa. In the US, the non-proprietary name for Sarclisa is isatuximab-irfc, with irfc as the suffix designated in accordance with nonproprietary naming of biological products guidance for industry issued by the US FDA.

Currently, Sarclisa is approved in more than 50 countries, including the US and EU, across two indications; Sarclisa is approved under an additional indication in the US. Based on the ICARIA-MM phase 3 study, Sarclisa is approved in combination with Pd for the treatment of patients with R/R MM who have received ≥2 prior therapies, including lenalidomide and a proteasome inhibitor, and who progressed on last therapy. Based on the IKEMA phase 3 study, Sarclisa is also approved in 50 countries in combination with carfilzomib and dexamethasone, including in the US for the treatment of patients with R/R MM who have received 1–3 prior lines of therapy and in the EU for patients with MM who have received at least 1 prior therapy. In the US, Sarclisa is approved in combination with bortezomib, lenalidomide, and dexamethasone (VRd) as a front-line treatment option for adult patients with newly diagnosed multiple myeloma (NDMM) who are not eligible for autologous stem cell transplant (ASCT), based on the IMROZ phase 3 study. On November 14, 2024, the European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the approval of Sarclisa-VRd in this patient population. A final decision is expected in the coming months.

Sanofi continues to advance Sarclisa as part of a patient-centric clinical development program, which includes several phase 2 and phase 3 studies across the MM treatment continuum spanning six potential indications. Further clinical studies evaluating a subcutaneous administration method for Sarclisa are ongoing.

In striving to become the number one immunoscience company globally, Sanofi remains committed to advancing oncology innovation. Through focused strategic decisions the company has reshaped and prioritized its pipeline, leveraging its expertise in immunoscience to drive progress. Efforts are centered on difficult-to-treat often rare cancers such as select hematologic malignancies and solid tumors with critical unmet needs, including multiple myeloma, acute myeloid leukemia, certain types of lymphomas, as well as gastrointestinal and lung cancers.

For more information on Sarclisa clinical studies, please visit www.clinicaltrials.gov.

About Sanofi

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across the world, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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